



Beiersdorf 758-HCL
100718-362
6713-Dr. Wi-hf

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

APPLICANTS : LANZENDÖRFER et al.
SERIAL NO. : 10/025,065
FILED : 19 December 2001
FOR : O/W EMULSIONS CONTAINING ONE OR MORE AMMONIUM
ACRYLOYLDIMETHYLAURATE/VINYLPYRROLIDONE
COPOLYMERS
ART UNIT : 1617
EXAMINER : Shaojia A. Jiang, Ph.D.

8 December 2003

Mail Stop: Appeal Brief - Patents
Hon. Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' BRIEF ON APPEAL PURSUANT TO 37 CFR § 1.192

SIR:

This is an appeal from the final rejection dated 6 May 2003.

(1) REAL PARTY IN INTEREST

The real party in interest is **Beiersdorf AG** by virtue of an assignment recorded on at Reel
012879, Frame 0533 (Recorded on 6 May 2002).

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals and interferences.

(3) STATUS OF CLAIMS

Claims 1 and 3-8 are under final rejection.

(4) STATUS OF AMENDMENTS

The amendments submitted on 22 May 2003 by the applicants after the examiner's final rejection were stated to be entered in the Advisory Action of 6 June 2003 (Paper No. 12).

(5) SUMMARY OF INVENTION

Note: All paragraph numbers refer to the U.S. publication of this application, i.e. U.S. Patent Application Publication 2002/0176832 (28 November 2002)

The present invention relates to a cosmetic or dermatological emulsion of the oil-in-water type comprising:

- (i) up to 90% by weight of a water phase,
- (ii) 0.5% to 20% by weight of a lipid phase, based on the total weight of the preparation,
- (iii) up to 10% by weight of one or more emulsifiers, and
- (iv) 0.2% to 0.3% by weight of one or more ammonium acryloyldimethyltaurates/vinylpyrrolidone copolymers.

Support for this claim can be found throughout the specification, e.g. original claim 1

Dependent claims 3-8 are supported throughout the specification with the following examples as follows:

- Claim 3: paragraph [0028]
- Claim 4: original claim 4
- Claim 5: original claim 5
- Claim 6: paragraph [0028]
- Claim 7: original claim 5
- Claim 8: original claim 5

(6) ISSUES

1. Whether the examiner erred in rejecting claims 1, 3 and 6 as being obvious over Beerse et al. (U.S. Patent 6,294,186)
2. Whether the examiner erred in rejecting claims 4, 5, 7 and 8 as being obvious over Beerse et al., *ibid.*, in view of Applicants' admission regarding the prior art.

(7) GROUPING OF CLAIMS

Claims 1 and 3-8 on appeal are directed toward a cosmetic or dermatological emulsion of the oil-in-water type. Claims 1, 3 and 6 will stand or fall together. For claims 4, 5, 7 and 8, it is believed that each of the dependent claims are allowable on the merits should the rejection of the independent claim be maintained.

(8) ARGUMENT

Summary

The appellants' believe that their claims are unobvious over the prior art and allegation of Applicants' admission because:

- (1) The examiner appears to be improperly holding the appellants to a "clear and convincing evidence" standard rather the proper "preponderance of evidence" standard in formulating her obviousness rejection.
- (2) The appellants' invention and the invention of Beerse appear not to have been taken as a whole and the obviousness rejection was built upon a faulty foundation of elements obtained by hindsight reconstruction from the Beerse reference.
- (3) The examiner relies on an "optimization of parameters" argument to remedy a deficiency in the Beerse reference but there is no recognition that this parameter is a results effective variable.
- (4) There is no factual basis that there would be a reasonable expectation of success to modify Beerse's teachings as suggested by the examiner.

- (5) Additionally, for dependent claims 4, 5, 7 and 8, the examiner appears to rely on an improper "could be combined" standard for modifying Beerse.

Restatement of the Facts

- (1) The elements of the appellants' invention as embodied in claims 1 and 4 are compared against the essential elements of Beerse's invention in the table below:

Appellants' claim 1	Beerse's claim 1 (same as Summary of Invention - see col. 3, lines 32-40)
A cosmetic or dermatological emulsion of the oil-in-water type comprising	
up to 90% by weight of a water phase	An antimicrobial composition comprising
	(a) a safe and effective amount of a benzoic acid analog
0.5% to 20% by weight of a lipid phase, based on the total weight of the preparation,	
	(b) a safe and effective amount of a metal salt; and
up to 10% by weight of one or more emulsifiers, and	
	(c) a dermatologically effective acceptable carrier for the acid and salt wherein said composition has a pH of from about 1 to about 7 and is substantially free of para-amino salicylic acid.
0.2% to 0.3% by weight of one or more ammonium acryloyldimethyltaurates	
Appellants' claim 4 (same as claim 1 and...)	
one or more dyes, coloring pigments, or a combination thereof	

- (2) Viewing Beerse in a light most favorable to maintaining the examiner's position, it could be argued that Beerse's composition intends to also cover cosmetic or dermatological use (see col. 4, lines 3-4) and that the carrier encompasses oil-in-water emulsions (see col. 12, beginning with line 13) albeit with specific limitations: (1) being acceptable for the acid and salt; (2) pH of about 1 to about 7; and (3) being substantially free of para-amino acid.
- (3) Reliance on the Beerse reference makes a presumption that all of the elements of the Beerse invention could also be inserted into appellants' invention, i.e. (a), (b) and the

three specific limitations with regard to the carrier of (c).

- (4) The only example of the use of an ammoniumacryloyldimethyltaurate/vinylpyrrolidone copolymer in the Beerse reference is Example 3 (see col. 48 - listed as "Aristoflex AVC") which is outside the range claimed by the appellants.
- (5) The Beerse reference lists a wide range of "optional components" from col. 19, line 51 through col. 44, line 25.
- (6) The examiner acknowledges that the Beerse reference does not teach the inclusion of one or more dyes, coloring pigments or a combination thereof as in the appellants claims (especially claim 4).

Standards for establishing a *prima facie* case of obviousness

MPEP 2141 states that "[w]hen applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
- (D) Reasonable expectation of success is the standard with which obviousness is determined."

MPEP 2142 establishes that three basic criteria must be met in order to establish a *prima facie* case of obviousness:

- (1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings;
- (2) There must be a reasonable expectation of success; and
- (3) The prior art reference must teach or suggest all the claim limitations.

MPEP 2142 also establishes that the legal standard for patentability is a “preponderance of evidence” standard and states that “With regard to rejections under 35 U.S.C. 103, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e. the reference teachings establish a *prima facie* case of obviousness) is more probable than not.

Rejection of claims 1, 3 and 6 over Beerse alone does not meet the above standards for establishing a *prima facie* case of obviousness

“Clear and convincing” vs. “Preponderance of Evidence” standards

The establishment of the *prima facie* case of obviousness appears to have been formulated using an erroneous standard, i.e. “clear and convincing evidence”. The examiner wrote in her Final Rejection (see page 5, lines 1-3 of Paper No. 10 - also reiterated in the Advisory Action): “Therefore, the evidence presented in the specification herein is not seen to be clear and convincing in support [of] the nonobviousness of the instant claimed invention over the prior art.”

However, “clear and convincing” as defined in *Black’s Law Dictionary* (5th Edition) means “proof beyond a reasonable, i.e. a well-founded doubt.” This is not the standard for obviousness which only requires a “preponderance of evidence” which MPEP 2142 defines as being more probable than not (which is also consistent with the definition of the phrase in *Black’s*), e.g. if the evidence of record is 50.01% in favor of non-obviousness and 49.99% in favor of obviousness, the claims should be held to be unobvious.

It is well known that the ultimate determination whether an invention would have been obvious under 35 U.S.C. § 103 is a legal conclusion based on underlying findings of fact (see *In re Kotzab*, 217 F.3d 1365, 1369, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000)). We now turn our attention as to whether the factual findings support the legal conclusion that the preponderance of evidence establishes a case of *prima facie* obviousness for the appellants’ invention.

“As a whole” standard

While the examiner is not limited to the claims in determining the teachings of a prior art

reference, MPEP 2141.02 directs the examiner to consider both the applicants' claimed invention and that of the prior art reference "as a whole" including portions that would lead away from the claimed invention. In addition, such reliance on the entirety of the prior art reference resides in what that reference "...would have **reasonably suggested** to one having ordinary skill in the art, including non-preferred embodiments." [emphasis added - citations omitted] see MPEP 2123.

When reading the Beerse reference "as a whole" without benefit of the appellants claims, one of ordinary skill in the art is directed towards compositions which must contain: (1) a "safe and effective" amount of a benzoic acid analog and a metal salt (or a metal-benzoic acid analog complex) ; and (2) a dermatologically acceptable carrier with a pH of from about 1 to about 7 and being substantially free of para-amino salicylic acid.

This differs greatly from the appellants claimed invention as only the "dermatologically acceptable carrier" limitation could arguably be considered to be a requirement of the applicants' claimed invention and even then it must be presumed that the appellants' emulsion is acceptable for the acid and salt, has the appropriate pH and is substantially-free of para-amino salicylic acid. Even if one were to give a generous interpretation to the appellants use of the term "comprising" this still does not address the fact that the amount of acryloyldimethyltaurates/vinylpyrrolidone copolymers in the respective inventions are different.

No recognition that parameter to be optimized is a results effective variable

The examiner argues that "the optimization of known amounts of known ingredients in a cosmetic composition according to the prior art herein is considered **well within the skill of artisan**, involving merely routine skill in the art. It has been held that it is within the skill in the art to **select optimal parameters**, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA)." (see page 2, last paragraph of Advisory Action (Paper No. 12).

The *Boesch* decision is also recited in MPEP 2144.05 II. (Optimization of Ranges) B. (Only Results Effective Variables Can Be Optimized) and is being applied improperly by the examiner as MPEP 2144.05 II.B. recites: "**A particular parameter must first be recognized as a result-effective variabl** , i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as

routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)...See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)."

The only recitation in Beerse for the use of acryloyldimethyltaurates/vinylpyrrolidone copolymers is in Example 3 of col. 48 (2%). There is no other recitation of use or of suggested ranges within the Beerse reference much less a recitation that this particular parameter is a results-effective variable which can be optimized. If there is some other factual basis for asserting that acryloyldimethyltaurates/vinylpyrrolidone copolymers were disclosed to be a results effective variable, this basis has never been communicated to the appellants.

No factual basis for reasonable expectation of success to modify Beerse reference

Beerse only serves as prior art based on the assumption that all of the elements of their invention are also included in the appellants' invention; there is no suggestion that one of ordinary skill in the art could practice Beerse's invention without a benzoic acid analog, a metal salt and a carrier with a pH of about 1 to about 7 and being substantially free of para-amino salicylic acid, i.e. the appellants claims also encompass oil-in-water emulsions without any of these elements.

Given the lack of teaching within Beerse for the use of acryloyldimethyltaurates/vinylpyrrolidone copolymers and the specific nature of the elements which comprise the invention of Beerse (safe and effective amount of benzoic acid analog, safe and effective amount of metal salt, carrier acceptable for analog and salt which has a pH of about 1 to about 7 and is substantially free of para-amino salicylic acid) there is no factual basis for asserting a reasonable expectation of success that modifying the amount of acryloyldimethyltaurates/vinylpyrrolidone copolymers would still result in an oil-in-water emulsion which contains the essential elements of Beerse's invention.

Rejection of claims 4, 5, 7 and 8 over Beerse in view of Applicants' admission does not meet the above standards for establishing a *prima facie* case of obviousness

The appellant's response to claims 1, 3 and 6 are also to be considered repeated here.

"Could be combined" or "obvious to try" is not the proper standard for obviousness

The examiner relies on an alleged admission by the appellants to supplement her

rejection with respect to Beerse to account for the difference between Beerse and the appellants' claimed invention which also includes one or more dyes, coloring pigments or a combination thereof. However, the "admission" only recites that certain dyes and coloring agents are known in the art not that it was known to add it to the emulsion claimed by the appellants.

What is lacking in Beerse or in the appellants' admission is a teaching or suggestion to add the dyes or colorants to Beerse's emulsion which is already under question as to whether it teaches the appropriate amount of acryloyldimethyltaurates/vinylpyrrolidone copolymers. The explanation offered by the examiner comes from hindsight reconstruction not from any particular recitation from the references. MPEP 2143.01 states that "The mere fact that references can be combined or modified does not render the resultant combination obvious ***unless the prior art also suggests the desirability of the combination.***"

While Beerse does mention colorants (see col. 20, line 4 and 10), it is only within the context of broad classes of optional components. It is also noted that Beerse recites more specific examples of these optional components which covers col. 20-44, none of which are directed to colorants much less any sort of description with regard to amounts of colorants or that the colorants should be used in combination with acryloyldimethyltaurates/vinylpyrrolidone copolymers. As such, the number of permutations from the basic elements of Beerse's invention is virtually limitless with no direction as to which additional ingredient to add.

In re Rice, 178 USPQ 478, 480 (CCPA 1973) also spoke to the issue of obviousness and hindsight reconstruction and stated that, "...the board said, referring to the appellant's ingredients, 'It should be noted that an infinite number of combinations is possible.' Accepting that as an approximation to the truth, we fail to see the obviousness in devising appellant's.....[invention] as claimed." *Id.* at 480.

Examiner's arguments that it was well within one of ordinary skill in the art or that it was obvious to try the suggested modification should not be given any weight as it has been established that neither of these standard are acceptable for making an assertion of obviousness. MPEP 2143.01 states that "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were known in the art is not sufficient to establish a *prima facie* case of obviousness without some

objective reason to combine the teachings of the references.” and MPEP 2144.05 X. states in part “[t]he admonition that ‘obvious to try’ is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been ‘obvious to try’ would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful....”

In addition claims 5, 7 and 8 recited ever narrower ranges of the amount of dyes or coloring pigments which are present in the appellants’ oil-in-water emulsion which is even further removed from the combination of Beerse and appellants’ admission.

(9) CONCLUSION

For the foregoing reasons, appellants respectfully request that the Honorable Board reverse the final rejections.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, appellants request that this be considered a petition therefor. Please charge the required petition fee to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess to our Deposit Account No. 14-1263.

Respectfully submitted,
NORRIS MCLAUGHLIN & MARCUS, P.A.

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Date: **8 December 2003**

By


Agata Glinska

(10) APPENDIX - CLAIMS ON APPEAL

1. A cosmetic or dermatological emulsion of the oil-in-water type, comprising
 - (i) up to 90% by weight of a water phase,
 - (ii) 0.5% to 20% by weight of a lipid phase, based on the total weight of the preparation,
 - (iii) up to 10% by weight of one or more emulsifiers, and
 - (iv) 0.2% to 0.3% by weight of one or more ammonium acryloyldimethyltaurates/vinylpyrrolidone copolymers.
3. The emulsion as claimed in claim 1, wherein its lipid content is 0.5% to 7.5% by weight.
4. The emulsion as claimed in claim 1, further comprising one or more dyes, coloring pigments, or a combination thereof.
5. The emulsion as claimed in claim 4, wherein the total amount of the dyes and coloring pigments is from 0.1% by weight to 30% by weight based on the total weight of the preparations.
6. The emulsion of claim 2, wherein said lipid content is 5-10% by weight.
7. The emulsion of claim 5, wherein said amount of dyes and coloring pigments is from 0.5 to 15% by weight.
8. The emulsion of claim 7, wherein said amount of dyes and coloring pigments is from 1.0 to 10% by weight.